Inspections, Compliance, Enforcement, and Criminal Investigations

King Systems Corp. 10/26/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 26 2009

WARNING LETTER

VIA FEDERAL EXPRESS

Flois Burrow
Owner/Chief Executive Officer
King Systems Corporation
15011 Herriman Blvd.
Noblesville, Indiana 46060-4253

RE: King LT(S)-D™ Oropharyngeal Airway
Refer to GEN0900697 when replying to this letter

Dear Ms. Burrow:

The Food and Drug Administration (FDA) has learned that your firm is marketing in the United States the King LT(S)-D oropharyngeal airway for uses that have not received marketing clearance or approval. in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

The Office of Compliance in the Center for Devices and Radiological Health (CDRH) reviewed your website, http:www.kingsystems.com, for the King LT(S)-D™ oropharyngeal airway product. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

Your firm has obtained 510(k) clearance for the following products and intended uses: King LT oropharyngeal airway (K021634), intended for use in adult patients for controlled ventilation during anesthesia for procedures of short duration, when the patient is considered to have a low risk of aspiration of stomach contents; and the King LT-D disposable oropharyngeal airway (K033186) and King LTS oropharyngeal airway (K033189), both intended for use in adult patients (in excess of 25 kg) for controlled ventilation during anesthesia for procedures that are short in duration and when the patient is considered to have a low risk of aspiration of stomach contents. King LT(S)-D™ Airway - Instructions For Use available on your website states that the "KING LTS-D is intended for airway management in patients over 4ft in height for controlled (30 cm H^20 or higher) or spontaneous ventilation. It is also indicated for difficult and emergent airway cases and is well suited for ambulatory and office-based anesthesia." This represents a major change or modification in the cleared intended use of the device and requires a new 510(k).

The device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the devices into commercial distribution, as required by sections 510(k) of the Act, 21 U.S.C. § 360(k), in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by section 510(k), 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

The Office of Compliance requests that King Systems immediately cease the dissemination of promotional materials for the King LT(S)-D Oropharyngeal Airway the same as or similar to those described above. You should take prompt action to

correct these violation(s). Failure to promptly correct these violation(s) may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil money penalties.

Please submit a written response to this letter within 15 working days from the date you receive this letter, describing your intent to comply with this request, listing all promotional materials for the King LT(S)-D™ Oropharyngeal Airway the same as or similar to those described above, and explaining your plan for discontinuing use of such materials. Please direct your response to the Food and Drug Administration, Jennifer R. Medicus, Chief, Radiology, Anesthesiology, and Neurology Devices Branch, Office of Compliance, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO66/2626, Silver Spring, MD 20993, facsimile at 301-847-8128. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for the King LT(S)-D™ Oropharyngeal Airway comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

/S/
Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health